supportive care after randomization and same D regimen after first evidence of PD). Primary endpoint was overall survival (OS). Additional analyses included tumor response, toxicity, progression-free survival (PFS) and quality of life (QoL).

Results: Table below summarizes results through May 6, 2007. Final data will be available in July. Enrollment totaled 564 patients; 393 patients received 4 cycles of GC therapy, and 308 patients were randomized equally to immediate D and delayed D groups. Patient demographics were well balanced between D arms. Initial GC therapy was well tolerated with major toxicities represented in myelosuppression, but only 7.7% of patients experienced G4 thrombocytopenia. D delivered immediately following GC therapy had a manageable toxicity profile comparable to the delayed D arm. Post-randomization, a notable number of patients in the delayed D arm (N=60) never received D therapy, mainly due to PD or personal decision to discontinue. PFS in the immediate D arm (6.0 months) was significantly greater (p=<0.0001) than in the delayed D arm (2.8 months). OS trended in favor of immediate D therapy (11.9 months) by 2.5 months compared to delayed D therapy (9.4 months), but was not statistically significant (p=0.1065). QoL average symptom burden index based on responses to a Lung Cancer Symptom Scale survey was not statistically different (p=0.43) comparing the two D arms.

Conclusions: NSCLC patients can be administered D immediately after first-line GC therapy without a sacrifice in either toxicity or QoL. While the PFS analysis for each D group suggests a possible clinical benefit for immediate D therapy, the OS result trended in favor of immediate D therapy, but did not reach statistical significance.

Characteristic/Result Initial GC Delayed D Immediate D

N enrolled/randomized	564	155	153
Mean age (range)	65 (36-87)	65 (36-85)	65 (41-87)
Performance status 0,1:2, %	89:11	89:11	93:7
Stage IIIB:IV, %	14:85	16:83	18:82
N assessed for safety	560	95	145
G3-4 Neutropenia, %	31.8	33.7	33.1
G3/G4 Thrombocytopenia, %	20.4/7.7	0/0	1.4/0
G3-4 Febrile neutropenia, %	1.8	1.1	3.5
G3-4 Anemia, %	13.0	0	0.7
G3-4 Fatigue, %	5.9	3.2	9.6
G3-4 Vomiting, %	2.3	1.1	0
G3-4 Diarrhea, %	0.4	5.3	0.7
G3-4 Neuropathy, %	0	0	0
G3-4 Myalgia, %	0.2	1.1	0.7
G3-4 Asthenia, %	2.1	1.1	2.1
N assessed for response	393	95	145
Overall response rate (CR+PR), %	38.9	9.5	11.7
N assessed for survival	-	155	153
Median OS, months	-	9.4	11.9
12 Month survival rate, %	-	41.2	48.3
Patients censored for OS, n (%)	-	25 (16.1%)	34 (22.2%)
Median PFS, months	-	2.8	6.0
Patients censored for PFS, n (%)	-	10 (6.4%)	9 (5.9%)

P2-306 **NSCLC: Cytotoxic Chemotherapy Posters, Tue, Sept 4**

Epoetin beta (EPO) together with Carboplatin/Gemcitabine (CaGem) chemotherapy for advanced NSCLC: A phase II study with matched controls

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Background: Previous data from our centre has shown that 50-60% of the patients require blood transfusion when treated with palliative chemotherapy. EPO has not been accepted for routine use in Denmark due to no shortage of blood for transfusions although the patients may have to accept low haemoglobin (Hb) values during treatment before transfusion. This may lead to reduced QOL and may lead to early stopping of treatment, and admissions which may be avoided with EPO. This study was initiated to study the use of EPO to prevent anaemia in not yet anaemic NSCLC patients undergoing chemotherapy. Investigated was not just the impact of EPO on the number of blood transfusions, but also the number of days admitted to hospital, cycles of chemotherapy and QOL.

Methods: In the EPO-group treatment with epoetin beta (NeoRecormon®) 30.000 IE s.c. was initiated if Hb<13 g/dL, and stopped if Hb>14 g/dL. 52 chemotherapy-naïve patients with advanced NSCLC scheduled for 6 courses of Carboplatin (AUC5, d1) and Gemcitabine (1000 mg/m^2) in PS=0-2 accepted inclusion in the study 3/2005 to 1/2007. A matched control group of 52 patients selected from a cohort of 195 patients treated 2003-2005 with CaGem without EPO. Criteria for matching were gender, Hb (</≥), PS (0-1/2), WBC (</≥10), stage (III/IV), LDH (</≥UNL), and weight loss (</≥5%).

Results: All together the study consisted of 104 patients, 52 in the EPO-group, and 52 in a matched control group: 38 patients fulfilled all 7 criteria for matching, 8 patients fulfilled 6 criteria, and 6 patients fulfilled 5 criteria. All pairs showed match with gender, Hb, and PS. One pair had no match for WBC, and 3 no match for stage, 7 for LDH and 11 for weight loss. The groups were very similar with regard to major criteria not matched for (Age 63.3 vs. 62.1 years, and BMI 24.0 vs. 24.5).

As of March 1st, 5 patients were still receiving CaGem in the EPO-group. 25 in the EPO-group had initial Hb<13g/dL and started with EPO during the first cycle of CaGem. Of the 27 patients presenting with Hb≥13g/dL, 21 patients received EPO after a median time of 26 days.

Survival of the EPO-group and controls were 7.6 and 7.4 months. 1 year survival was 38% and 37%. Preliminary analyses showed the transfusions dropped 43% from 0.95 portion blood to 0.54 per given cycle CaGem (p=0.16) The number of cycles of CaGem per patient who had fulfilled chemotherapy March 1st was 4.4 cycles in the EPO group and 4.0 in the control group (0.20). Final analyses will be performed July 31st.

Conclusions: The matched pair design worked. Preliminary analyses showed a trend to less transfusions, and trend to being able to receive more chemotherapy when EPO was applied